VenaCure EVLT

Endovenous Laser Treatment System

THE POWER OF WATER

THE INDUSTRY LEADER IN
ENDOVASCULAR LASER ABLATION

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VenaCure® 1470 Laser
The Power of water

VenaCure EVLT
Endovenous Laser Treatment System

The new VenaCure 1470nm laser from AngioDynamics may result in even better patient outcomes for physician's, with all the same features and reliability that made the Delta laser such a success.

AngioDynamics is not only a pioneer in the laser vein ablation market, we're also the world's largest endovenous laser ablation company.

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VenaCure EVLT
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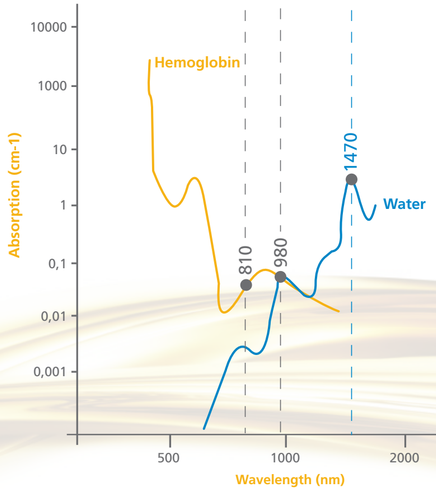
All the features you love

The VenaCure 1470 laser has all the features you love about the Delta laser platform: the Fibre Recognition System (FRS), which facilitates fewer steps enabling a shorter procedure set-up; the high-performance design; and the controls and interconnects, which were kept to a minimum and carefully placed, making the interface simple and easy to use. Like the Delta laser, the VenaCure 1470 laser helps physicians treat patients with ease.

Heats the Vein Wall to Ablation Temperature Faster[1]



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The VenaCure 1470nm laser is a water-specific laser, meaning it damages the intima, or inner most layer of the vein, by targeting water as the chromophore to absorb the laser energy. Since the vein structure is mostly water, this laser is able to efficiently heat the vein with little chance of collateral heating, resulting in an optimal vein ablation.

The VenaCure 1470nm laser is designed to work exclusively with AngioDynamics[2] NeverTouch and NeverTouch Direct fibres and perforator ablation kits, maximising these two technologies may result in even better patient outcomes. The 1470nm laser allows effective vein ablation with increased efficiency and precisely delivers the targeted energy of 30-50 joules/cm through the NeverTouch fibre at a setting of 5-7 watts.[1]

VenaCure 1470 Laser Features & Benefits

Fibre Recognition System (FRS)†

- Faster procedure set-up with preset parameters
- Immediate recognition of procedure presets
- Protective door helps prevent dust particles from damaging laser or fibre

Quality

- Industry-leading standard warranty ensures every laser will receive top-notch service
- Internal sensors constantly monitor wattage ensuring a constant energy output
- More than 20 safety features at and above standard

Easy to use

- Intuitive user interface with fewer buttons
- Programmable sound pulses allows for audible tracking of pull-back rate which increases repeatability of treatment
- Aiming beam with variable modes and brightness increases visibility in patient
- Real-time on-screen display of treatment energy

Lightweight, Compact and Portable

- Easily transported between hospital and office

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NeverTouch® Gold-Tip Fibre

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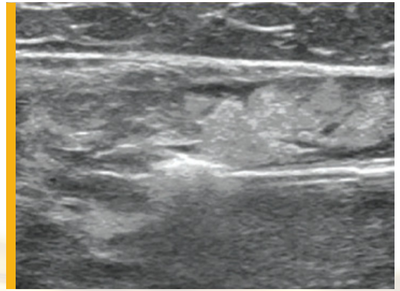
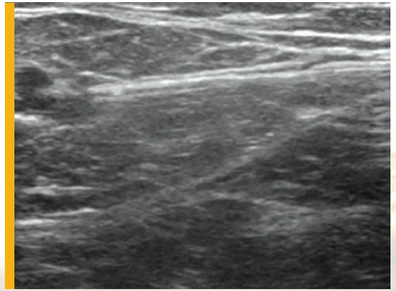
The NeverTouch Gold-Tip Fibre

The gold-tip fibre eliminates inadvertant laser tip contact with the vein wall.

The gold-tip also maximises visibility under ultrasonic visibility, making it easier for physicians to use.[1,3]





Echogenic

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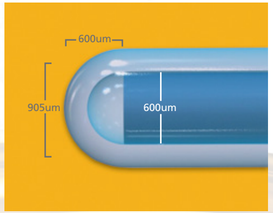
The Proprietary Science Behind NeverTouch Fibres

The innovation behind the NeverTouch fibre is a glass weld at the distal tip of a 600 um fibre. The weld results in an effective fibre diameter of 905 um and lowers the actual power density by 56 percent from that of a standard bare tip 600 um fibre. The net effect, based on bench testing*, is a homogeneous ablation with less focal charring of the vein wall than that which is seen with bare tip fibres. This technology is exclusive to AngioDynamics and is different from competitors with other covered tip fibres that have the same power density as a 600 um fibre.*



* Bench testing results may not be indicitive of clinical performance.
All claims based on bench test data on file.
Testing completed by AngioDynamics.

The NeverTouch Fibre Can Successfully Treat Larger Veins

VenaCure EVLT
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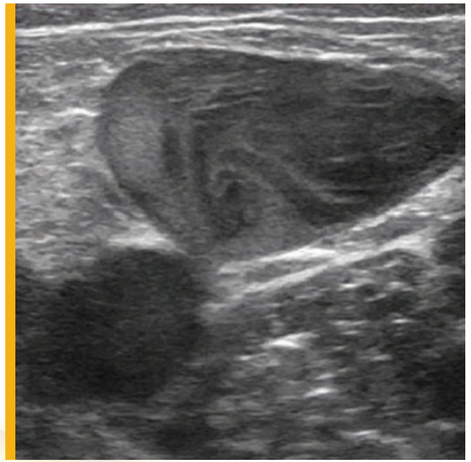
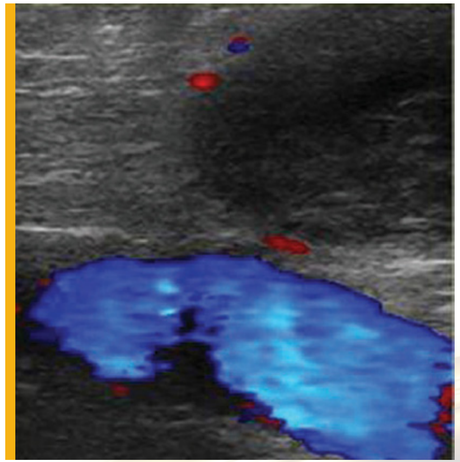


BEFORE
39.2 mm GSV before



AFTER
Vein after Venacure 1470 laser procedure with NeverTouch fibre

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NeverTouch Procedure Kit Features and Benefits

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Micro-access system in convenient "kangaroo pouch"

Select from a variety of micro-access kits, all packaged on the outside in a separate sterile pouch.

NeverTouch-FRS fiber

Fiber recognition system is compatible with all AngioDynamics' lasers.

Sheath-Lok system

Enables precise placement at the saphenofemoral junction by locking the fiber to the sheath, assuring the fiber stays a safe distance outside the sheath.

Sliding sheath gauge

Aids in marking treatment length and holding sheathin place during tumescent anesthesia.

Available with a 21 or 19 gauge needle

New 19 gauge needle now available for physicians who prefer to insert the .035" wire directly through the needle.

4F TRE-Sheath hydrophilic-coated introducer

(translucent, radiopaque, echogenic) Echogenic for easy positioning and hydrophilic coating to reduce procedure time.

Stainless steel braid

Improves pushability through tortuous anatomy and increases echogenicity.

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NeverTouch® Direct

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Go Direct: Fewer Steps. Less Time.

All the benefits of the NeverTouch fibre.

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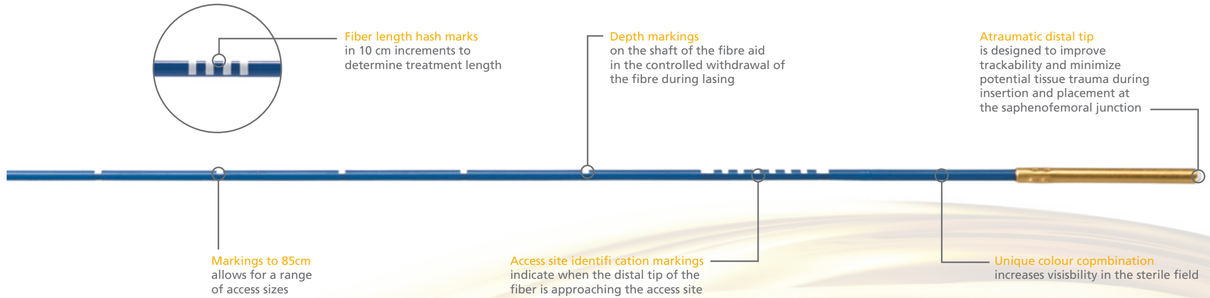
VenaCure EVLT
Endovenous Laser Treatment System

NeverTouch Direct Fibre

- Provides same benefits as the NeverTouch fibre, now with an atraumatic tip for sheathless placement
- Allows physicians to advance to the saphenofemoral junction without the use of a TRE-Sheath® introducer in appropriate patients
- Allows physicians to gain access, advance the fibre and treat a diseased vein without the placement of a second guidewire
- Fewer components result in fewer procedure steps and potentially result in faster procedures


Fiber length hash marks
in 10 cm increments to
determine treatment length
Depth markings
on the shaft of the fibre aid
in the controlled withdrawal of
the fibre during lasing
Atraumatic distal tip
is designed to improve
trackability and minimize
potential tissue trauma during
insertion and placement at
the saphenofemoral junction
Markings to 85cm
allows for a range
of access sizes
Access site identifi cation markings
indicate when the distal tip of the
fiber is approaching the access site
Unique colour copmbination
increases visisbility in the sterile field

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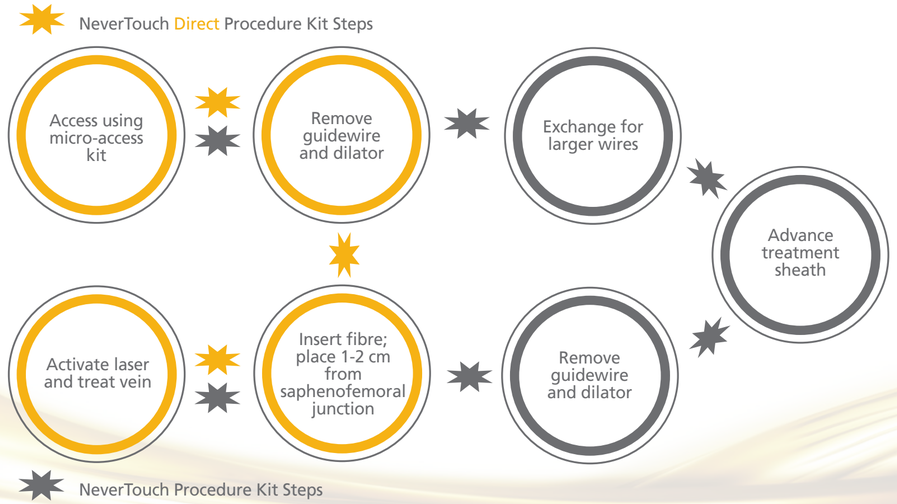
Procedure Steps:
NeverTouch Direct Kit vs. NeverTouch Kits†

Fewer procedure steps may result in a reduction of procedure time


NeverTouch Direct Procedure Kit Steps
Access using micro-access kit
Remove guidewire and dilator
Exchange for larger wires
Advance treatment sheath
Remove guidewire and dilator
Insert fibre; place 1-2 cm from saphenofemoral junction
Activate laser and treat vein
NeverTouch Procedure Kit Steps

† The above is an abbreviated representation of the steps to reat a vein with the VenaCure EVLT system.
All the steps necessary to successfully treat a varicose vein have not been included.

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The Proprietary Science Behind NeverTouch Fibres

The innovation behind the NeverTouch fibre is a glass weld at the distal tip of a 600 um fibre. The weld results in an effective fibre diameter of 905 um and lowers the actual power density by 56 percent from that of a standard bare tip 600 um fibre. The net effect, based on bench testing*, is a homogeneous ablation with less focal charring of the vein wall than that which is seen with bare tip fibres. AngioDynamics' patent-pending technology is different from competitors with standard covered-tip fibres that have the same power density as a 600 um fibre.+

* Bench testing results may not be indicitive of clinical performance.
All claims based on bench test data on file.
Testing completed by AngioDynamics.

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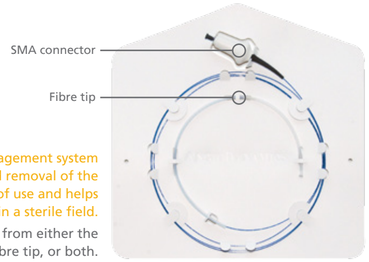
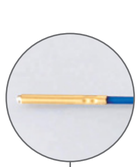
NeverTouch Direct Procedure Kit Features and Benefits

New procedure kit package designed with physician feedback increases usabillity and functionality:

- Separate micro-access components packaging reduces waste
- Stackable boxes with a smaller package footprint makes storage more efficient





NeverTouch Direct Fibre

Never Touch Direct Fibre with a Blue Nylon Jacket.

SMA connector

Fibre recognition system is compatible with all AngioDynamics lasers

The new fibre management system allows for controlled removal of the fibre to increase ease of use and helps maintain a sterile field.

Access in the sterile field from either the SMA connector or fibre tip, or both.

4F 10cm Nylon Introducer/dilator

45 cm .018" nitinol/ stainless steel wire

The .018" wire tips are atraumatic, designed to deflect off the vessel wall.

21G echogenic access needle in Stainless Steel

Available for physicians who prefer to insert the NeverTouch Direct wire directly through the needle.

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400 µm Fiber Procedure Kit

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Treat Superficial Veins with the Precision of the VenaCure EVLT System

Superficial Veins (SV) associated with Chronic Venous Insufficiency (CVI) are linked to venous hypertension, severe sequelae of CVI, and the development of leg ulcers[4]. Treatment of CVI/SV can lead to reduced recurrence rates for venous ulcers[5]. This represents a significant opportunity to expand the range of venous disease treated in your practice.

Treat SV with the 400 µm Fiber Procedure Kit, part of the VenaCure EVLT system:

- 400 µm low-profile fiber allows for simple access and positioning
- Office-based procedure using local anesthesia

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Procedure kits and Laser

VenaCure EVLT
Endovenous Laser Treatment System

Part Number	Description	Box Quantity

LASER

The 1470 Laser is intended for use in the treatment of varicose veins and varicosities with superficial reflux of the Greater Saphenous Vein, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limb.

VCURE1470/XX	VenaCure EVLT 1470 Laser with Fibre Recognition System (FRS) and 1 year manufacturer's warranty. Accessories included with each laser	1

STANDARD KIT – VenaCure EVLT Kits & fibres

The NeverTouch Procedure Kit is indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

11403001	NeverTouch FRS w/21g needle and .018'' Micro access Guidewire & Micro introducer Sheath PLUS .035'' wire Long access Double ended Guidewire & 4F TRE-Sheath Introducer with Dilator (Distal Tip 600 µm Fibre); 45cm Standard Kit	5
11403002	NeverTouch FRS w/21g needle and .018'' Micro Access Guidewire & Micro introducer Sheath PLUS & .035'' wire Long access Double ended Guidewire & 4F TRE-Sheath Introducer with Dilator (Distal Tip 600 µm Fibre); 65cm Standard Kit	5
11403004	NeverTouch FRS w/21g needle and .018'' Micro Access Guidewire & Micro introducer Sheath PLUS .035'' wire Long access Double ended Guidewire & 4F TRE-Sheath Introducer with Dilator (Distal Tip 600 µm Fibre); 90cm Standard Kit	3

PROCEDURE KIT – NeverTouch Direct

The NeverTouch Direct Procedure Kit is indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

11403101	NeverTouch Direct FRS w/21g needle, .018'' 45 cm nitinol/stainless steel wire and 4F 10 cm introducer/dilator; 85cm Fibre	1

VenaCure EVLT
Endovenous Laser Treatment System

Part Number	Description	Box Quantity

PROCEDURE KIT – VenaCure EVLT Kits & fibres

The NeverTouch Procedure Kit is indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

11403005	NeverTouch FRS w/19g needle,.035" Long Access Double-ended Guidewire and 4F TRE-Sheath Introducer with Dialator (Distal Tip 600 µm Fibre); 45cm Kit	5
11403006	NeverTouch FRS w/19g needle, .035" Long Access Double-ended Guidewire and 4F TRE-Sheath Introducer with Dialator (Distal Tip 600 µm Fibre); 65cm Kit	5
11403007	NeverTouch FRS w/19g needle, .035" Long Access Double-ended Guidewire and 4F TRE-Sheath Introducer with Dialator (Distal Tip 600 µm Fibre); 90cm Kit	1
11403003	NeverTouch FRS w/21g needle, .018" Long Access Guidewire and 4F TRE-Sheath Introducer with Dilator (Distal Tip 600 µm Fibre); 25cm Kit	5
11403012	NeverTouch FRS w/21g needle, .018" Long Access Guidewire and 4F TRE-Sheath Introducer with Dilator (Distal Tip 600 µm Fibre); 45cm Kit	5
11403013	NeverTouch FRS w/21g needle, .018" Long Access Guidewire and 4F TRE-Sheath Introducer with Dilator (Distal Tip 600 µm Fibre); 65cm Kit	5

PROCEDURE KIT – 400µm fibre

400µm is intended for use in the treatment of varicose veins and varicosities associated with superficial vein reflux of the Great Saphenous vein, and with veins in the lower limbs with superficial reflux.

EVLT/PVAK	VenaCure EVLT 400µm - PVAK RFID w/21g needle, .018'' Micro Access Guidewire & 4F Micro Introducer Sheath with Dilator (Bare-Tip 400 µm Fibre); 10 cm	5

AngioDynamics' VenaCure EVLT endovenous laser vein treatment offers patients a minimally-invasive choice for treating the source of their varicose veins and provides them with quicker recovery and a return to normal daily routines as compared to surgical stripping. The VenaCure EVLT system includes 1470 nm and 810 nm lasers, a choice of procedure kits, procedure accessories, marketing materials and support, and more. For more information on these products, including our proprietary NeverTouch fibre technology, please visit www.VenaCure-EVLT.com.

IMPORTANT RISK INFORMATION
INDICATION FOR USE: The AngioDynamics, Inc. VenaCure EVLT NeverTouch Procedure Kits are indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremity. This product should be used only with lasers cleared for use in the treatment of varicose veins, varicosities with superficial reflux of the GSV, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower limbs.
CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.

CAUTION: This device is ethylene oxide sterilized and intended for single patient use only. Do not reuse or resterilize the fibres.
Contents sterile in unopened, undamaged package. Do not use if opened or any sign of product damage is visible. Carefully read all directions and observe all Warnings and Precautions prior to performing the procedure.
POTENTIAL COMPLICATIONS: Adverse reactions may include, but are not limited to: vessel perforation, thrombosis, pulmonary embolism, phlebitis, hematoma, infection, skin pigmentation alteration, neovascularization, paresthesia due to thermal damage of adjacent sensory nerves, anesthetic tumescence, non-target irradiation, vasospasm, hemorrhage, necrosis, skin burns and pain.
Indications, contraindications, warnings and instructions for use can be found in the instructions for use supplied with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.

CONTRAINDICATIONS: Patients with thrombus in the vein segment to be treated, patients with an aneurysmal section in the vein segment to be treated or patients with peripheral artery disease as determined by the Ankle Brachial Pressure Index with a value of <0.9 should not have their varicosities ablated.
WARNINGS AND PRECAUTIONS: Treatment of a vein located close to the skin surface may result in skin burn. Tissue not targeted for treatment must be protected from injury by direct and reflected laser energy. All persons in the treatment room MUST wear protective glasses with the proper rating for the wavelength being used.

VenaCure EVLT

Endovenous Laser Treatment System

angiodynamics

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tel: +31 (0)20 753 2949 > fax: +31 (0)20 753 2939

www.angiodynamics.com

References:

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2. An Update on Endovenous Laser Ablation Update by Mikel Sadek, MD, Lowell S. Kabnick, MD.
3. EVL Ablation Using jacket-Tip Laser Fibres by Lowell S. Kabnick, MD, FACS, FACPH, and Jayne A. Caruso, RN.
4. Nelzen O. Prospective study of safety, patient satisfaction, and leg ulcer healing following Saphenous and SEPS. British Journal of Surgery 2000; 87:86-91.
5. Barwell J, et al. ESCHAR Study: randomized controlled trial. The Lancet June 2004; 63:1854-59.

† User Manual.

+ Data on file.

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